

REMARKS

Claims 1, 3-9, 11, 12, 14-19, 21, 22, 24, 25, 27-48 and 50-52 will be pending upon entry of this Letter To Patent And Trademark Office. No claims have been amended. Applicants respectfully request reconsideration and allowance of all pending claims.

1. Rejection of the Claims 1, 3-9, 11-12, 14-18, and 51-52 under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1, 3-9, 11-12, 14-18, and 51-52 under 35 U.S.C. §103(a) as being unpatentable over Pospischil (U.S. Patent 3,803,300) in view of Horizumi (EP 1,136,057) and Watanabe (JP 61-176512).¹

Claim 1 is directed to a single-use lip treatment product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material, from about 0.01% by weight to about 50% by weight of a moisturizing agent, and from about 0.1% by weight to about 50% by weight of a solidifying agent. The single-use lip treatment product is a film and comprises a single layer. The product is capable of being substantially dissolvable on lips in no more than about 50 seconds. The single-use lip treatment product is sized and configured for application to the lips, and the solidifying agent is selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax,

¹ Claim 19 has not been specifically rejected within the text of the instant Office action, however, claim 19 has been indicated as being rejected in the Office Action Summary. As such, the patentability of claim 19 in light of the cited references has been discussed herein.

beeswax C₃₀ alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite parrafin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnuba wax, synthetic japan wax, solid fatty acid esters, fatty alcohols, fatty acids, copolymers or polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof.

Pospischil discloses ointment foils for application to injured or intact skin. The ointment bodies are foil-shaped in accordance with their normal applications and are emulsions of the oil-in-water type, that is, they have a fat or oil phase colloiddally dispersed in a continuous aqueous phase although their water content may be as low as 1% and should not be higher than 15% by weight. The foil-shaped bodies comprise water and other conventional ointment ingredients, such as 20% to 60% of a pharmaceutically acceptable oily or fatty ointment base, 2% to 12% of an emulsifier capable of emulsifying the base in water, **3% to 20% of a film forming agent**, 12% to 40% of a humectant, and 1% to 15% of an active agent of any type conventionally employed in ointments for therapeutic or cosmetic purposes and compatible with the other ingredients. The oil-in-water emulsions may contain enough titanium oxide or zinc oxide to make them opaque. Film forming agents which have been used successfully in the foil-shaped bodies of the invention include polymers having repeating carboxyvinyl groups, methyl cellulose,

carboxymethyl cellulose and other water soluble cellulose derivatives, vegetable mucilage, alginates, polyvinyl pyrrolidone, copolymers of vinyl pyrrolidone and vinyl acetate, agar, carragheen, dextran, and the like. Significantly, Pospischil fails to disclose or suggest a product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material and a solidifying agent selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax, beeswax C₃₀ alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite parrafin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnuba wax, synthetic japan wax, solid fatty acid esters, fatty alcohols, fatty acids, copolymers or polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof. These are significant aspects of Applicants' invention.

Recognizing that Pospischil fails to teach or suggest each and every limitation of claim 1, the Office attempts to combine the Pospischil reference with Horizumi and Wantanabe for a *prima facie* case of obviousness. Horizumi discloses a sheet cosmetic comprising an aqueous gel sheet in the absence of a supporting layer that is highly adhesive to the skin, assumes a transparent appearance, provides no sense of incongruity when applied to the skin, and achieves excellent moistening and cooling effects on

the skin. The sheet includes an agar ingredient (A) of a 1.5 wt% agar content. Gel-forming materials including the agar ingredient (A) are incorporated into the sheet cosmetic preferably in a total amount of 0.01-5 wt%. The sheet cosmetic may further contain a water-soluble polymer (B) so as to improve strength and storage stability thereof. The water-soluble polymer (B) is incorporated into the sheet cosmetic preferably in an amount of 0.001-50 wt%, **particularly 0.01-10 wt%**. The sheet cosmetic may further contain a humectant (C) or other ingredients such as organic acids, oil, sterols, a surfactant, powder, silicones, inorganic salts, a preservative, a pH-regulator, a UV-absorber, a colorant, a pharmaceutically active ingredient, and a perfume. The sheet may be formed into an arbitrary shape, and the cosmetic is applied directly to the skin of a washed face or is applied to a portion of the skin where another cosmetic has already been applied. It should be noted that when applied to the face, the sheet is provided with holes corresponding to the eyes, the nose, and the mouth. As such, when applied to the face, the lips are not being treated.

Watanabe discloses a film-forming agent comprising a polymeric compound; a humectant; and an oleaginous wax for providing moisture to lips, and to further prevent abnormal drying and chapping of lips. Examples of polymeric compounds that can be used to form the film-forming agent can include PVA, polyvinyl pyrrolidone, and CMC. Furthermore, the humectant has excellent moisture-retainability and is effective to give moistness to the dried skin and can be, for example, glycerol, propylene glycol, polyethylene glycol, and sorbitol. The oleaginous wax is effective in supplying the skin with a

moderate amount of oil to prevent chapping of the skin. Suitable waxes include olive oil, jojoba oil, lanoline, and squalane. The skin film is applied to the lip mucous membrane surface and then the skin film is peeled off the surface of the lip, either prior to or after the film has dried, to treat the lips.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385, 1396 (2007) noted that the burden lies initially with the Office to provide an explicit analysis supporting a rejection under 35 U.S.C. 103. "[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."² The Court in *KSR International* further identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966)). Specifically, as previously required by the TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art reference that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at each and every limitation of the claimed invention. Specifically, to

reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as there is no apparent reason for one skilled in the art to modify and/or combine the reference teachings to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

The Office states at page 4 of the instant Office action that one of ordinary skill in the art at the time of the invention would have found it obvious to provide water-soluble polymers in higher amounts as taught by Horizumi in the composition of Pospischil and to further include an oleaginous wax as taught by Wantanabe in order to increase the strength of the composition as taught by Horizumi. Applicants respectfully disagree. As noted above, although Horizumi broadly discloses the inclusion of a water-soluble polymer in an amount of 0.001 wt% to about 50 wt%, Horizumi expressly discloses that the preferred amount of the water-soluble polymer is significantly less than the upper range that is broadly disclosed.

² In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

Specifically, Horizumi discloses that it is preferable to include 0.01 wt% to 10 wt% of the water-soluble polymer. As such, why would one skilled in the art be motivated to include a water-soluble polymer in any amount between 40% and 70% when Horizumi discloses that the preferred amount does not exceed 10%? One simply would not and could not be so motivated.

Further, even if Horizumi did provide an enabling disclosure of its broadest range of water-soluble polymer, Horizumi specifically mentions including a hole for the mouth when using the product on the face; that is, Horizumi is not directed to treating the lips. Moreover, Wantanabe is the only reference that even mentions treating of the lips, but includes significantly lower amounts of a film-forming agent than is required by Applicants' claim 1. As such, why would one skilled in the art look to the Wantanabe reference, which is used to treat the lips, for combination with the Horizumi reference, which includes a hole for the lips so that the lips are not being treated? One skilled in the art simply would not and could not be so motivated.

In addition, the Examiner states at pages 4-5, regarding the limitation of the capability of the composition to substantially dissolve in a certain amount of time, that one skilled in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount and type of the ingredients provided in the sheet composition, according to the guidance provided by Pospischil, Horizumi and Wantanabe, to provide a composition having desired dissolving properties, such as a desired dissolving duration.

While Applicants recognize that in *In re Aller*, the Court generally states that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation," Applicants assert that the Office must first consider that the particular parameter was **recognized** as a result-effective variable before the determination of the optimum or workable ranges of the parameter might be characterized as routine experimentation; that is, the cited references must recognize the need for modifying and/or optimizing the amount and type of ingredients provided in the sheet composition prior to determining the type and optimum or workable ranges of the ingredients.³ According to the present invention, the single-use lip treatment product has a rate of dissolution once applied to the lips such that the product substantially dissolves in an amount of time short enough to be satisfactory to consumers. No where, however, do the cited references even mention a rate of dissolution or the need/desire of such a property. As such, one skilled in the art simply would not and could not be motivated to modify and/or optimize the amount and type of ingredients to arrive at Applicants' claim 1 based on the teachings of the cited references.

Moreover, a close reading of the references actually teaches away from a combination of at least the Pospischil and Horizumi references as the compositions and products produced therein are designed to solve substantially different problems using different mechanisms. For example, Horizumi discloses

³ MPEP §2144.05(II) (B), citing *In re Antonie*, 195 USPQ 6 (CCPA 1977).

that their sheet cosmetics, which provide no sense of incongruity, have a light transmittance of 70% or more. Horizumi explains that this is necessary because when the light transmittance is less than 70%, the sheet assumes no transparent appearance and provides considerable incongruent sensation when applied to the skin. In direct opposition, however, the Pospischil reference discloses that the oil-in-water emulsions of their invention may contain enough titanium oxide or zinc oxide to make them opaque. As such, one skilled in the art, reading the Horizumi and Pospischil references, would not, and could not, reasonably be motivated to combine these references to arrive at Applicants' claim 1.

As there is no motivation or apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1, claim 1 is patentable over the cited references.

Claims 3-9, 11, 12 and 14-18 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

Claims 19, 51, and 52 are similar to claim. Accordingly, claims 19, 51, and 52 are patentable over the cited references for the same reasons as claim 1, as well as for the additional limitations they require.

Further, claim 52 requires the single-use lip treatment product to include from about 60% by weight to about 65% by weight of a water-soluble film forming polymeric material and a solidifying agent selected from the group consisting of animal

waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax, beeswax C₃₀ alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite paraffin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnauba wax, synthetic japan wax, solid fatty acid esters, fatty alcohols, fatty acids, copolymers or polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof.

Significantly, none of the cited references disclose or suggest a product comprising from about 60% by weight to about 65% by weight of a water-soluble film forming polymeric material. At best, the Pospischil reference discloses that their ointment may comprise 3-20% of a film forming agent, the Horizumi reference discloses that their sheet cosmetic comprises a water-soluble polymer in an amount of 0.001 wt% to 50 wt%, particularly 0.01 wt% to 10 wt%, and the Wantanabe reference discloses that their lip-protective agent may comprise 15% or less by weight of a polymer such as poly (vinyl alcohol), polyvinylpyrrolidone, or cellulose⁴, all amounts of which are well below the amount required by Applicants' amended claim 52.

As none of the cited references disclose or suggest a single-use lip treatment product that comprises from about 60%

⁴ See, e.g., Id. at Examples 1-5. Specifically, water-soluble film forming polymers are present in the compositions in the concentrations as follows: Example 1: 15% by weight; Example 2: 15% by weight; Example 3: 13% by weight; Example 4: 15% by weight; and Example 5: 15% by weight.

by weight to about 65% by weight of a water-soluble film forming polymeric material as required by claim 52, claim 52 is patentable over the cited references for this additional reason.

2. Rejection of the Claim 51 under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claim 51 under 35 U.S.C. §103(a) as being unpatentable over Fox (U.S. Application Publication No. 2004/0071755) in view of Horizumi (EP 1136057) and Watanabe (JP 61-176512).

Claim 51 is directed to a single-use body treatment product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material, from about 0.01% by weight to about 50% by weight of a moisturizing agent, and from about 0.1% by weight to about 50% by weight of a solidifying agent. The single-use body treatment product is a film and further comprises a single layer. The solidifying agent is selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax, beeswax C₃₀ alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite paraffin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnauba wax, synthetic japan wax, solid fatty acid esters, fatty alcohols, fatty acids, copolymers or polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof.

Fox discloses a water soluble sheet or film for use in the personal care field. The water soluble sheets include a "base composition" that includes from about 0.75% to about 5% by weight of a water soluble film forming polymer; from about 6.5% to about 23% by weight of polyvinyl alcohol; and from about 0.75% to about 12% by weight of a humectant such as propylene glycol.⁵ Suitable materials for use as the water soluble film forming polymer include polyvinylpyrrolidone (PVP), polyquaternium 10, magnesium aluminum silicate, VP/VA copolymer, ethyl ester of PVM/MA copolymer, and sodium magnesium silicate.⁶ Furthermore, the base composition can be used with a variety of surfactants, which when exposed to water, will dissolve and provide personal cleansing such as can be obtained from a soap bar or a liquid body wash.⁷ Significantly, Fox fails to disclose a product comprising **from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material and a solidifying agent selected from the group consisting of animal waxes, vegetable waxes, mineral waxes, synthetic waxes, bayberry wax, beeswax C₃₀ alkyl dimethicone, candelilla wax, carnauba, ceresin, cetyl esters, esparto, hydrogenated cottonseed oil, hydrogenated microcrystalline wax, hydrogenated rice bran wax, japan wax, microcrystalline wax, mink wax, motan acid wax, motan wax, ouricury wax, ozokerite paraffin, PEG-6 beeswax, PEG-8 beeswax, rezowax, rice bran wax, shellac wax, spent grain wax, spermaceti wax, steryl dimethicone, synthetic beeswax, synthetic candelilla wax, synthetic carnauba wax, synthetic japan wax,**

⁵ U.S. 2004/0071755 at paragraph 9.

⁶ *Id.* at paragraph 10.

⁷ *Id.* at paragraph 6.

solid fatty acid esters, fatty alcohols, fatty acids, copolymers or polymeric blends of ethylene, propylene, butylene, styrene, or vinyl acetate, and combinations thereof. These are significant aspects of Applicants' invention.

Recognizing that Fox fails to teach or suggest each and every limitation of claim 51, the Office attempts to combine the Horizumi and Watanabe references with Fox for a *prima facie* case of obviousness. Horizumi and Watanabe are discussed above.

Initially, as noted above, Fox fails to teach or suggest a product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material. More particularly, as noted above, the compositions of Fox comprise from about 0.75% to about 5% by weight of a water soluble film forming polymer (e.g., polyvinylpyrrolidone) and from about 6.5% to about 23% by weight of polyvinyl alcohol, which are listed as examples of water-soluble film forming polymeric materials in Applicants' claimed invention. As such, the maximum amount of water-soluble film forming polymeric material for use in the composition as taught in the Fox reference is 28% by weight. Furthermore, as shown in all of the working Examples in the Fox reference, the water soluble film forming polymer is present in the base composition in an amount of about 15.66% by weight (i.e., 1.75% PVP K-30 + 13.91% AirVol 523S (polyvinyl alcohol)). More specifically, the final products produced in the working Examples of the Fox reference teach even lower amounts of water soluble film forming polymers. Specifically, the working Examples show that the base composition is present in the final composition in amounts of from about 19.5-21% by weight. Thus, the compositions set forth in Fox have significantly lower

percentages of water-soluble film forming polymeric materials than the products set forth in Applicants' claim 51. Based on this disclosure, there is no apparent reason for one skilled in the art to avoid preparing the compositions of Fox having less than 40% by weight of water-soluble film forming polymeric material, in direct opposition to the products set forth in Applicants' claim 51.

Furthermore, while the Applicants recognize that the base composition is dried onto the final product, no where in the cited reference is it taught or suggested to what extent the base composition is dried. Specifically, no where in Fox is the final water content of the product disclosed. As such, there is no teaching or suggestion that enough water is removed during the drying process to result in the final product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material as required in claim 51.

Horizumi and Watanabe fail to overcome this shortcoming as there is no motivation to combine the Horizumi, Wantanabe, and Fox references to arrive at Applicants' claim 51.

The Office states at page 6 of the instant Office action that one of ordinary skill in the art at the time of the invention would have found it obvious to provide water-soluble polymers in higher amounts as taught by Horizumi in the composition of Fox and to further include an oleaginous wax as taught by Wantanabe in order to increase the strength of the composition as taught by Horizumi. Applicants respectfully disagree. As noted above, although Horizumi discloses the inclusion of a water-soluble polymer in an amount of 0.001 wt% to about 50 wt%, Horizumi further discloses that the preferred

amount of the water-soluble polymer is significantly less than the upper range that is broadly disclosed. Specifically, Horizumi discloses that it is preferable to include only 0.01 wt% to 10 wt% of the water-soluble polymer. As such, why would one skilled in the art be motivated to include a water-soluble polymer in an amount between 40% and 70% when Horizumi disclose that the preferred amount does not exceed 10%? One simply would not and could not be so motivated.

Furthermore, even if one skilled in the art could be motivated by Horizumi to combine the teachings of Fox and Wantanabe and to increase the amount of water-soluble polymer (which, as noted above, Applicants assert is clearly not the case here) there is still no clear articulated reason for combining the cited references. More specifically, the lip products of Watanabe (and, the single-use lip or body treatment products of the present invention) include a solidifying agent to help solidify the product at or near room temperature. At best, Fox discloses that soap and synthetic surfactant may be added to the base composition until the point at which film formulation, and consequently, the formation of the soluble sheet product, is adversely effected. Fox continues to explain that soap can be the sole surfactant added to the base composition, or, alternatively, it may be combined with another surfactant for addition to the base composition. Compatible soaps include sodium octonate and potassium soaps. In contrast to the teaching in Watanabe (and, to the present invention), the purpose of adding the surfactant to the composition of Fox is to aid the disclosed body wash in producing a lather for cleansing. As such, why would one skilled in the art be motivated to

combine Fox to include a solidifier from the group as recited in Watanabe (or as required in Applicants' claim 51), which are included to solidify the presently composition at room temperature? There is simply no reason to do so.

Moreover, according to Horizumi, as well as the present invention, the water-soluble polymer improves the strength of the product. By contrast, Fox is directed to a body wash, which is intended to be rinsed from the skin after application. Accordingly, the high amounts of the water soluble and/or water-dispersible film forming polymeric material would be unnecessary in the composition of Fox, and could actually be considered **undesirable** as it would hinder the ability of the body wash to be washed from the skin. As including these higher amounts of water soluble and/or water-dispersible film forming polymeric materials into the body wash of Fox would produce an inferior product as what is already taught by Fox, one skilled in the art would actually be motivated to not increase these amounts. Accordingly, a close reading of the Fox reference may actually teach away from such a modification. With all due respect, it appears that the Office has merely used impermissible hindsight and reconstruction (using the Applicants' claimed invention as a blueprint) for arriving at such a combination. The federal Circuit has consistently warned against this kind of analysis.

As there is no apparent reason for one skilled in the art to modify/combine the compositions of the references to arrive at the compositions of claim 51, claim 51 is patentable over the cited references.

CONCLUSION

In light of the foregoing, Applicants request withdrawal of the rejections of claims 1, 3-9, 11, 12, 14-19, 21, 22, 24, 25, 27-48 and 50-52 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required to Deposit Account No. 01-2384.

Respectfully Submitted,

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